

**REMARKS UNDER 37 CFR § 1.111**

**Formal Matters**

Claims 1, 6-10, 12-16, 31, 33, 35, 37-39, 41-42, 44-45, 50, 52-53, 55, 59, 62, 64-72, 74-76, 78-79, 84, 86, 88-95, 104-120, 122 and 124-151 are pending after entry of the amendments set forth herein.

Claims 1, 6-10, 12-16, 31, 33, 35, 37-39, 41-42, 44-45, 50, 52-53, 55, 59, 62, 64-72, 74-76, 78-79, 84, 86, 88-95, 104,106, 113-114 and 124-151 are currently withdrawn from consideration by the Examiner.

Claims 2-5, 11, 17-30, 32, 34, 36, 40, 43, 46-49, 51, 54, 56-58, 60-61, 63, 73, 77, 80-83, 85, 87, 96-103, 121 and 123 have been canceled, without prejudice to the possibility of filing one or more continuing applications directed to the subject matter recited therein.

Claims 107-112 and 115-123 were examined.

Claims 107-112 and 115-123 were rejected.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

**The Office Action**

**Claims Rejected Under 35 U.S.C. Section 112, Second Paragraph**

In the Official Action of 08/01/2011, claim 108 was rejected under 35 U.S.C. Section 112, second paragraph as being indefinite. The Examiner noted that “the expandable member” lacked antecedent basis.

In response thereto, claim 108 has been amended to change “the expandable member” to --the expandable device—for which there is literal antecedent basis in claim 107.

In view of the above amendment and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claim 108 under 35 U.S.C. Section 112, second paragraph, as being indefinite, as being no longer appropriate.

**Objection to Drawings**

The Examiner objected to the drawings as not showing a guidewire, sheath, looped tabs, rod or wire, or splittable jaws. The Examiner required that these features be shown in the drawings or canceled from the claims.

In response thereto, Applicants are submitting herewith New Fig. 3 that shows sheath 3 and guidewire 5. No new matter has been added. The specification has been amended to comport with the new Fig. 3. Regarding looped tabs, rod or wire, and splittable jaws, Applicants have canceled claims 121 and 123 above, without prejudice to the possibility of filing one or more continuing applications directed to the subject matter recited therein.

In view of the above amendments and remarks and submission of new Fig. 3, the Examiner is respectfully requested to reconsider and withdraw the objection to the drawings as being no longer appropriate.

**Claims Rejected Under 35 U.S.C. Section 102(b) (Berson)**

Claims 107-110, 112 and 115-116 were rejected under 35 U.S.C. Section 102(b) as being anticipated by Berson, U.S. Patent No. 4,246,893.

The Examiner asserted that Berson teaches making a percutaneous opening in the abdominal cavity of the patient at column 4, lines 54-56.

Applicants respectfully traverse. It is respectfully submitted that column 4, lines 54-56 of Berson disclose placing the patient under general anesthesia and making an incision in the midline of the abdomen between the xiphoid process and the umbilicus. It is respectfully submitted that Berson fails to disclose making a percutaneous opening, contrary to the Examiner's assertion, and that the large incision disclosed by Berson is a general surgical technique, not a percutaneous one.

To further clarify these distinctions, claim 107 has been amended above to recite puncturing the skin of the patient and making a percutaneous opening to the abdominal cavity of the patient. Support for puncturing the skin can be found, for example, at paragraph [0032] and throughout the specification and drawings. Claim 110 recites making a minimally invasive opening to the abdominal cavity of the patient. It is respectfully submitted that the making of an incision in the midline of the abdomen between the xiphoid process and the umbilicus by Berson is the making of a minimally invasive opening. Berson makes the incision large enough such that the distensible balloon 2, together with the

filling tube 3 can simply be placed in the abdominal cavity in position, see column 4, lines 56-59.

The Examiner further asserted that Berson passing an expandable device 2, while in a contracted configuration, through the opening.

Applicants respectfully traverse. The Examiner did not identify where Berson discloses that the device 2 is in a contracted configuration when placed (or passed through an opening), nor have Applicants been able to locate such a disclosure. In fact, there is no disclosure of inflating the device 2 at any time during the placement surgery. At column 5, lines 19-22, Berson discloses that after recovery from the initial surgery, the patient may be treated to increase or decrease (emphasis added) the amount of inflation of the balloon 2. This implies that the balloon was placed while in an inflated condition.

The Examiner further asserted that Berson discloses anchoring the expandable device 2 to at least one structure in the abdominal cavity, via port 4 by attaching suture 28 to tube 3 and nozzle 9.

Applicants respectfully traverse. It is respectfully submitted that the device 2 is not anchored by the tube 2 or nozzle 9 because the device 2 is not prohibited from moving toward the nozzle by this arrangement, even after the sutures are thrown. To still further clarify this distinction, claims 112 and 115 have been amended above to recite that the device (or at least a portion of the expandable member) is drawn into contact with a location of the structure that it is anchored to. Support for these amendments can be found, for example, at paragraph [0034] and throughout the specification and drawings.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 107-110, 112 and 115-116 under 35 U.S.C. Section 102(b) as being anticipated by Berson, U.S. Patent No. 4,246,893, as being inappropriate.

#### **Claims Rejected Under 35 U.S.C. Section 103(a) (Berson)**

Claims 111, 117 and 120 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Berson, U.S. Patent No. 4,246,893.

As to claim 111, the Examiner asserted that Berson discloses the invention as claimed except for wherein at least two locations on the expandable device are anchored to at least one structure in the abdominal cavity.

Applicants respectfully traverse. For at least the same reasons provided above with regard to claim 110 (Berson does not make a minimally invasive opening) it is respectfully submitted that Berson does not disclose the invention of claim 111 except for anchoring at two locations, since claim 11

depends from claim 110.

The Examiner further argued that it would be mere duplication of parts to anchor the device of Berson at two locations.

Applicants respectfully traverse. As Berson does not fix the position of the balloon 2 by anchoring, for reasons provided above, anchoring to two locations would not be mere duplication of parts, but would rather improve the localization of the balloon. Berson does not teach the importance of securely placing the balloon 2, since Berson does not anchor the balloon at all. As noted above, the balloon is free to drift toward the nozzle 9. It is only incidental that the balloon 2 is tethered to the nozzle 9 by the tubing 3, this being necessary in order to deliver fluid from the nozzle 9 to the balloon 2. There is no indication that this arrangement of Berson is provided for anchoring or fixing a position, nor does it result in fixing a position of the balloon 2.

Regarding claim 117, the Examiner admitted that Berson does not disclose a laparoscopic procedure, but the Examiner asserted that it would have been obvious to perform the procedure of Berson laparoscopically. The Examiner asserted that it is well-known to do so. However the Examiner did not supply any reference that predates the present invention that supports the Examiner's position. Accordingly, it is respectfully submitted that the Examiner has failed to set forth a prima facie case of obviousness with regard to claim 117. It is further respectfully submitted that claim 117 is allowable over Berson for at least the same reasons provided above with regard to claim 115, since claim 117 depends from claim 115.

Regarding claim 120, the Examiner asserted that Berson discloses the invention as claimed except for a second expandable member.

Applicants respectfully traverse. For at least the same reasons provided above with regard to claim 115 (Berson does not anchor the balloon in contact against a location of the structure) it is respectfully submitted that Berson does not disclose the invention of claim 120 except for providing a second expandable member.

Further, the Examiner asserted that it would have been mere duplication of parts to use more than one anchor.

Applicants note that claim 120 does not recite a second anchor. Accordingly, it is respectfully submitted that the Examiner has failed to set forth a prima facie case of obviousness with regard to claim 120. It is further respectfully submitted that it would not have been "mere duplication of parts" to provide a second expandable member, as the present specification notes that there are advantages to be obtained by this, such as shaping and clustering to form a compressive barrier, where the expandable

devices are sized and shaped to complement each other, e.g., see paragraph [0026] and throughout the specification and drawings.

Accordingly, in view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 111, 117 and 120 under 35 U.S.C. Section 103(a) as being unpatentable over Berson, U.S. Patent No. 4,246,893, as being inappropriate.

**Claims Rejected Under 35 U.S.C. Section 103(a) (Berson in view of Grobe)**

Claims 119 and 122 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Berson, U.S. Patent No. 4,246,893 in view of Grobe, U.S. Patent No. 5,112,310.

The Examiner asserted that Berson teaches the method of claim 115.

Applicants respectfully traverse, for at least the same reasons provided above with regard to claim 115.

The Examiner admitted that Berson fails to teach or disclose inserting a sheath and a guidewire. However, the Examiner asserted that Grobe teaches these steps and that it would have been obvious to use these steps in Berson to reduce pain and shorten recovery time.

Applicants respectfully traverse. Grobe teaches a method of percutaneous endoscopic gastrostomy. As such, Grobe does not teach a percutaneous procedure for delivering a balloon such as the balloon of Berson. The Examiner asserted that this is well-known, but Grobe does not teach it and the Examiner has not provided any other reference to support the assertion. Accordingly, it is respectfully submitted that the Examiner has failed to set forth a prima facie case of obviousness with regard to claims 119 and 122.

Accordingly, in view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 119 and 122 under 35 U.S.C. Section 103(a) as being unpatentable over Berson, U.S. Patent No. 4,246,893 in view of Grobe, U.S. Patent No. 5,112,310 as being inappropriate.

**Conclusion**

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-2653, order number EXPL-004.

Respectfully submitted,

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